INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

[Date notice sent to all parties]:

01/07/2015 and 01/12/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Prisliq, Fentayl, hydrocodone, Metaxolone

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: Board Certified PMR and Pain Management

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Urine drug screen records xxxx
Radiographs pelvis xxxx
Clinical record Dr. xxx, DC xxxx
Clinical record Dr. xxxx, DC xxxxx

Radiographs lumbar spine 02/25/08
MRI lumbar spine 02/26/08
Clinical record Dr. xxx, MD 03/10/08
Clinical record Dr. xxxx, MD 03/24/08
Procedure report 04/16/08
Procedure report clinical record Dr. xxxx, MD 05/01/08
Procedure report clinical record Dr. xxxx, MD 05/08/08
Operative procedure report 05/20/08
Clinical record Dr. xxxx, MD 05/23/08
Electrodiagnostic studies 05/30/08
Clinical record Dr. xxxx, MD 06/30/08
Clinical record Dr. xxxx, MD 06/16/08
Clinical record Dr. xxxx, MD 05/26/09
MRI lumbar spine 02/25/09
Psychological evaluation Dr. xxxxx, PsyD 08/26/10
Clinical record Dr. xxxx, MD 12/09/11
Clinical record Dr. xxxx, MD 01/17/12
Clinical record Dr. xxxxx, MD 01/31/12
Clinical record Dr. xxxx, MD 05/01/12
Clinical record Dr. xxxx, MD 05/08/12
Clinical record Dr. xxx, MD 06/19/12
Clinical record Dr. xxxx, MD 09/27/12
Clinical record Dr. xxxx, MD 10/18/12
Clinical record Dr. xxxx, MD 10/22/12
Required medical evaluation Dr. xxxx, MD 12/27/12
Clinical record Dr. xxxx, MD 03/21/13
Clinical record Dr. Gopalani, MD 06/10/13
Clinical record Dr. Gopalani, MD 08/09/13
Clinical record Dr. Gopalani, MD 08/30/13
Clinical record Dr. Gopalani, MD 12/05/13
Clinical record Dr. Gopalani, MD 03/03/14
Clinical record Dr. Gopalani, MD 03/20/14
Letter xxxx, RN 11/14/14
Clinical record Dr. Gopalani, MD 06/09/14
Clinical record Dr. Gopalani, MD 10/01/14
Clinical record Dr. Gopalani, MD 11/11/14
Prior utilization reviews 10/21/14 and 12/05/14
Clinical records from another patient xxxxx

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a 43 year old female who sustained an injury on xxx when she tripped and fell developing complaints of low back pain. The patient was followed

by Dr. xxxx for an extended period of time for chronic low back pain complaints. Previous inject previous treatment included multiple injections and continuing medications including diazepam, fentanyl 50mcg/hour patch, hydrocodone 10/325mg four times a day, lorazepam .5mg, Pristiq 100mg, Skelaxin 800mg, valium 5mg, Zolpidem 12.5mg, and Zyrtec. Previous urine drug screen testing was last performed on 03/05/14 which noted positive findings for fentanyl, hydrocodone and benzodiazepines. The clinical evaluation from 11/11/14 noted the patient had the inability to perform multiple activities of daily living without medications. Pain score was reported 6/10 in severity. The patient described good efficacy with medications. Physical examination noted tenderness in the left paraspinal musculature with prior surgical scars. There was loss of lumbar spine range of motion. Mild weakness was evident at the left EHL 4/5. There was weakness on left dorsiflexion with heel walking. Left plantarflexion was weak when walking on toes. There was sensory loss in L5 distribution. The record indicated that with medications her pain was reduced from 8 to 10/10 to 4 out of 4 to 5/10. The patient was unable to tolerate weaning below the current prescribed fentanyl 50mcg/hour patch and hydrocodone 10/325mg four times a day. The patient had urine drug screens at almost every visit with random drug screen with random drug screens and pill counts which were all compliant. The patient was also prescribed Pristiq due to depression associated with chronic pain. The patient also described insomnia secondary to pain for which Ambien was prescribed.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

In regards to the continued use of narcotic medications including fentanyl hydrocodone the clinical records establish the efficacy of the medications. The patient has reduced pain scores by at least 50% with the use of hydrocodone and fentanyl for breakthrough and long term pain control. The patient is currently at the lowest possible dose tolerated even with weaning. The clinical records note consistency with random pill counts and urine drug screen testing. No aberrant medication use was described. Given the improvement in functional abilities and reduction in pain with compliance the continued use of fentanyl and hydrocodone would be appropriate based on guideline recommendations. Therefore it is the opinion of this reviewer that continued use of fentanyl and hydrocodone is medically necessary and the prior denials are overturned regarding this many these medications. In regards to the continued use of Pristiq the patient is reported to have depression associated with chronic pain. Pristiq is an antidepressant medication which is frequently utilized in chronic pain patients. Given the complaints of depression associated with chronic pain and as the patient has been utilizing Pristiq for an extended period of time this reviewer would not recommend continued use of this medication in association with depression due to chronic pain. Therefore it is the opinion of this reviewer that Pristiq is medically necessary and the prior denials are overturned. In regards to Metaxolone, the chronic use of muscle

relaxers is not recommended by current evidence based guidelines. At most, muscle relaxers are recommended for short term use only. The efficacy of chronic muscle relaxer use is not established in the clinical literature. There is no indication from the clinical reports that there has been any recent exacerbation of chronic pain or any evidence of a recent acute injury. Therefore, it is this reviewer's opinion that this medication is not medically necessary and the prior denials are upheld.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

☒ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

☒ ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Antidepressants for chronic pain
Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-*Cochrane*, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. (Perrot, 2006) (Schnitzer, 2004) (Lin-*JAMA*, 2003) (Salerno, 2002) (Moulin, 2001) (Fishbain, 2000) (Taylor, 2004) (Gijsman, 2004) (Jick-*JAMA*, 2004) (Barbui, 2004) (Asnis, 2004) (Stein, 2003) (Pollack, 2003) (Ticknor, 2004) (Staiger, 2003) Long-term effectiveness of anti-depressants has not been established. (Wong, 2007) The effect of this class of medication in combination with other classes of drugs has not been well researched. (Finnerup, 2005) The "number needed to treat" (NNT) methodology has been used to calculate efficacy of the different classes of antidepressants. (Sindrup, 2005) See also the Stress/Mental Chapter: Antidepressants for the treatment of depression. Also see Comorbid psychiatric disorders.
Specifically studied underlying pain etiologies: (also see below for

specific drugs)

Neuropathic pain: Recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007) Other recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007)

Non-neuropathic pain: Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose. (Perrot, 2006)

Specific studied disease states

Fibromyalgia: There have been 25 controlled trials that have studied the use of antidepressants for fibromyalgia, including 3 meta-analyses. Good results were found with duloxetine in fibromyalgia. (Arnold, 2007) Severa studies evaluated tricyclics. (Perrot, 2006) (Moulin, 2001) A review of two double blind, placebo controlled trials concluded that duloxetine was safe and effective in women with fibromyalgia for up to 12 weeks (with long-term studies needed). (Arnold, 2007) (Saarto-Cochrane, 2007) Duloxetine is approved by the FDA for treatment of fibromyalgia. (FDA 2010) Another review indicated that there is strong evidence that amitriptyline is effective for fibromyalgia and suggested that more information is needed regarding the role of SNRIs and SSRIs. (Goldenberg, 2007) Compared with placebo, the SNRIs duloxetine (Cymbalta) and milnacipran (Savella) are slightly more likely to reduce pain in patients with fibromyalgia, according to a new Cochrane meta-analysis, but they are not superior in terms of reducing fatigue and sleep problems or in improving quality of life, and they appear to cause more adverse effects. (Häuser, 2013)

Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. (Chou, 2007) Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial. (Perrot, 2006) *Acute:* Not routinely recommended. (Chou, 2007)

Radiculopathy: Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. (Dworkin, 2007)

Osteoarthritis: No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. (Perrot, 2006) In depressed

patients with osteoarthritis, improving depression symptoms was found to decrease pain and improve functional status. (Lin-JAMA, 2003)

Antidepressant discontinuation*:* Nearly all classes of antidepressants have been linked to discontinuation reactions that are distinct from recurrence or relapse of underlying psychiatric pathology. It does appear that discontinuation reactions can occur regardless of the particular indication for use. The most common research involves discontinuation of serotonin-reuptake inhibitors (Sertonin-discontinuation syndrome).

Symptoms: Symptoms of discontinuation vary between classes of antidepressants, and between different drugs in the classes. These may include changes in mental/psychological status (confusion, restlessness, agitation, anxiety, worsening of mood, panic attacks, dysphoria, manic symptoms, and decreased level of consciousness), neurological changes (tremor, rigidity, clonus, myoclonus, hyperreflexia, ataxia, and rigidity), autonomic changes (diaphoresis, shivering, mydriasis, nausea and diarrhea), and changes in vital signs (tachycardia, hypertension, hyperthermia, and tachypnea). Commonly patients describe both psychological and somatic symptoms (the latter described as flu-like, with or without gastrointestinal physical symptoms). Symptoms are thought to occur in at least 20% to 25% of patients upon discontinuing of serotonin-reuptake inhibitors (with reports of at least 50% with drugs with shorter-half lives such as paroxetine or venlafaxine). Symptoms tend to emerge within 2 to 5 days with a usual duration of 1 to 2 weeks. The primary risk factors for this reaction include use of antidepressants with shorter half-lives, longer duration of treatment, and abrupt discontinuation.

Differentiation from depression relapse or recurrence: Differentiating factors include looking for symptoms that are more likely to occur with discontinuation reaction (dizziness, electric shock-like sensations, “rushing” sensations, headache and nausea) as well as observing for rapid reversal of symptoms (complete resolution within 1 to 2 weeks of the taper/discontinuation is less likely to be due to depression). Later onset of symptoms (after at least two to three weeks of discontinuation/tapering) or prolonged symptoms (3 weeks or greater) are more commonly associated with a relapse of psychiatric pathology or another intercurrent disease. See also Weaning of medications (antidepressants) in the Mental Chapter for more information and references.

Opioids, criteria for use

CRITERIA FOR USE OF OPIOIDS

Therapeutic Trial of Opioids

1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:

(a) Are there reasonable alternatives to treatment, and have these been tried?

(b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?

(c) Is there likelihood of abuse or an adverse outcome? See Substance abuse (tolerance, dependence, addiction).

(d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has had a psychological evaluation and has been given a diagnosis of somatoform disorder. (3) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression).

(e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

2) Steps to Take Before a Therapeutic Trial of Opioids:

(a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.

(b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.

(c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.

(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.

(e) Pain related assessment should include history of pain treatment and effect of pain and function.

(f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.

(g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns

exist, a second opinion with a pain specialist and a psychological assessment should be obtained.

(h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

(i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.

(j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.

3) Initiating Therapy

(a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.

(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.

(c) Only change 1 drug at a time.

(d) Prophylactic treatment of constipation should be initiated.

(e) If partial analgesia is not obtained, opioids should be discontinued.

4) On-Going Management. Actions Should Include:

(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.

(b) The lowest possible dose should be prescribed to improve pain and function.

(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. <u>The 4 A's for Ongoing Monitoring</u>: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial

functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)

(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.

(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).

(g) Continuing review of overall situation with regard to nonopioid means of pain control.

(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse.

5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):

(a) Every 2 weeks for the first 2 to 4 months

(b) Then at approximate 1 ½ to 2-month intervals
Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)

6) When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. The patient should not be abandoned.

(a) If there is no overall improvement in function, unless there are extenuating circumstances

(b) Continuing pain with the evidence of intolerable adverse effects

(c) Decrease in functioning

(d) Resolution of pain

(e) If serious non-adherence is occurring

(f) The patient requests discontinuing

(g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.

(h) Many physicians will allow one "slip" from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.

(i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (Weaver, 2002)

(j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

7) When to Continue Opioids

(a) If the patient has returned to work

(b) If the patient has improved functioning and pain
(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)

Muscle relaxants (for pain)

Recommend non-sedating muscle relaxants with caution as a second-line option for short-term (less than two weeks) treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter.

Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Schnitzer, 2004) (Van Tulder, 2004) (Airaksinen, 2006) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in *American Family Physician*, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)
Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006)

ANTISPASMODICS: Used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. (Chou, 2004)

Metaxalone (Skelaxin®, generic available) is reported to be a relatively non-sedating muscle relaxant. The exact mechanism of action is unknown, but the effect is presumed to be due to general depression of the central nervous system. Metaxalone was approved by the FDA in 1964 and data to support approval were published in the mid-1960s. (Toth, 2004)
Side Effects: Dizziness and drowsiness, although less than that compared to other skeletal muscle relaxants. Other side effects include headache, nervousness, nausea, vomiting, and GI upset. A hypersensitivity reaction (rash) has been reported. Use with caution in patients with renal and/or hepatic failure.
Dosing: 800 mg three to four times a day (See, 2008)